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In-Licensing Human Drug Products For Development in Animal Health—A Cautionary Tale

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Animal Health Landscape has Changed

- Massive market creating paradigm shift in veterinary care for companion animals
- Pets are being humanized; “pet parents” continue to spend more and more money to keep their “children” healthy
- And yet over 90% of medicines used by vets are human drugs adapted by the vet for use in animals without FDA approval

Outlicensing Trend Has Birthed New Companies

- Human drug markets are still significantly larger than animal health markets
- Value of the animal health deal is less than providing access to a human indication, but can help fund the human drug development

➡ Bottom Line: Expect that any transaction will be designed to protect the human drug market

Six Key Considerations in Outlicensing A Human Drug for the Animal Health Market

1. Adjusting the Scope of the Field
2. Addressing Regulatory Overlap
3. Parsing out Patent Prosecution and Litigation
4. Sharing Product Supply
5. Handling Recall and Product Liability
6. Navigating Termination Scenarios and Insolvency

1. Adjusting The Field

- Issue: Human health companies frequently assume that they can parse out animal health fields using the same mechanism as they would for a different indication for human application

Understanding The Field

- Animal health may be divided by
  - Indication
  - Diagnostic, prophylactic, and therapeutic uses
  - Type of animal -- species, livestock, test subjects, or companion animals
  - Marketing channels – veterinary, pet specialty, retail and big box
- Human health company should:
  - Retain rights for all applications of the technology for humans
  - Retain rights for use of products in animal studies

Examples: Field of Use

- **1.10** "**Licensee Field of Use**" means the field of animal health.
- **1.35 "Field of Use"** shall mean the field of non-human animal health.
- **1.27** "**Field**" shall mean all prophylactic or therapeutic uses of the Licensed Product for veterinary use. For the avoidance of doubt, the Field shall not include use of the Licensed Product in humans.
- **1.13 "Aratana Field"** shall mean non-human animal health applications. Notwithstanding the foregoing, the Aratana Field shall exclude the conduct of GLP-compliant nonclinical laboratory studies that support, or are intended to support, applications to conduct human clinical research of an investigational human pharmaceutical product or to obtain marketing authorization for a human pharmaceutical product.

2. Addressing Regulatory Overlap

- Issue: Human health companies frequently assume that they will be able to benefit from the data generated by the animal health company seeking approval

Assume the data won't be useful. . .

- It is unlikely that data produced in studies seeking approval for an animal health product will be useful for your human health product development
- Even assuming the animal model for the human disease is the species that the partner is seeking to get the animal drug approval, the data collected is not necessarily the same as would be useful for human applications
- In other words, good results for animal health submissions are unlikely to have value, but bad results will reflect poorly on your product

Risk Mitigation

- Ensure that the agreement provides
  - you have access to data in the event that it is useful or in the event it is required to submit to regulatory authorities and
  - you have oversight on publications your partner may wish to make
  - confidentiality around your product information

3. Parsing out Patent Prosecution and Litigation

- Issue: The value of preserving the animal health field through patent enforcement will rarely be outweighed by the damage that could be inflicted on the human health protection

Risk Mitigation:

- Create set of “umbrella patents” which provide protection over both human and animal health drugs and provide human health company with control over patent prosecution and litigation
- Create a subset of patents that are truly specific to the animal health product that can be enforced without creating a road map to invalidity for the human health or umbrella patent families

Example of Patent Prosecution

- Licensor will have the right to control filing, prosecution, and maintenance of the Licensed Patents, including any patents and applications based on Licensor Improvements, at Licensor’s expense.
- Licensee will have the right to control filing, prosecution, and maintenance of patents and applications based on Licensee Improvements, at Licensee’s expense.

Example of Patent Prosecution (Cont.)

- The Non-Prosecuting Party will receive upon reasonable request and in any event on a quarterly basis a reasonably detailed report on patent prosecution matters.
- The Non-Prosecuting Party will have the opportunity to comment on any response to office actions or amendments to claims prior to their filing.
- The Non-Prosecuting Party will have the right to inspect the records kept by the Prosecuting Party and its patent counsel pertaining to the patents and patent applications licensed to the Non-Prosecuting Party.
- If the Prosecuting Party elects to abandon any application or patent licensed to the other party, the Non-Prosecuting Party will have the right to continue prosecution or maintenance of such application or patent at the Non-Prosecuting Party's sole expense.

Example of Patent Enforcement Licensor Don't

- The party who is the exclusive licensee of such licensed patent within the field of use subject to the infringement action (the "Enforcing Party") will retain sole control over enforcement and defense of the patent against such third party infringers. If the Enforcing Party files or defends any claim, suit, or action (a "Claim") against any third party based on any licensed patent, the other party (the "Non-Enforcing Party") will cooperate with the Enforcing Party, at the Enforcing Party's request, in enforcing or defending such Claim, including joining the Enforcing Party as a party to such suit or action to the extent necessary to establish standing.

4. Sharing Product Supply

- Issue: Sharing product supply when there is plenty is easy, consider what occurs when;
  - Shortage of supply of product or active
  - Reduced volume of supply due to failure of human health product
  - Consumers/pharmacists/vets recognize that the products are identical and view the supplies as interchangeable

Risk Mitigation

- Agreement can simply provide for
  - Separate supply
  - Metrics for allocation of supply
  - Use of a differentiated formulation that makes it particularly suitable for a patient subpopulation
- Keep in mind, if the human product fails, even if the animal health product doesn’t fail, it may not be cost effective for the human health company to manufacture your product

Example – Supply

- Aratana shall be solely responsible, at its sole expense, for all aspects of manufacturing of [Products] for use in the Aratana Field. In furtherance of the foregoing, promptly following the Effective Date, Advaxis shall provide Aratana with an introduction to Advaxis's Third Party contract manufacturer for [Products] and shall deliver to such contract manufacturer written authorization to contract with Aratana for the manufacture and supply of [Products]. . .and to disclose to Aratana such Advaxis Know-How regarding manufacture of [Products]. . ..

Example – Allocation of Supply

- In the event that Supplier is unable to supply the quantity of the Product ordered by Company for any particular month, then the Product available for such month shall be allocated between Company and Supplier (including its Affiliates and distributors outside the Field) pro rata on the basis of (a) the aggregate quantities of the Product ordered by Company for use in the Field in the immediate prior twelve (12) months, and (b) the aggregate quantities of the Product ordered by Supplier (including its Affiliates and distributors outside the Field) for use outside the Field in the prior twelve (12) months.

5. Handling Recall and Product Liability

- Issue: The partner's recall and product liability issues will reflect on your product but may or may not truly reflective of your product

Risk Mitigation:

- Ensure transparency through notice provisions
- Include requirement for clear communications of scope and rationale for recall
- Elucidate differences between animal health and human health products to be in a position understand whether both are implicated
- Have a thoughtful crisis communications plan

Example -- Product Withdrawals and Recalls.

- In the event that any Regulatory Authority threatens or initiates any action to remove any Product from the market in any country in the Territory, and in the event that a Party is notified of a material Product Complaint,
- the Party who receives the notice shall notify the other Party of such event within [***] after becoming aware of the action, threat, or requirement (as applicable).
- Licensor shall consult with Elanco prior to initiating a recall or withdrawal of Product in any country or regulatory jurisdiction in the Territory;
- provided, however, that the final decision as to whether to recall or withdraw a Product shall be made (i) by Licensor for the U.S. and the EU prior to the applicable [***] for Product in such countries, and (ii) by Elanco (A) at any time after the Effective Date for all countries other than the U.S. and the EU

6. Navigating Termination Scenarios and Insolvency

- Issue: If the human health company starts to fail, it will use its resources to protect the human health franchise rather than the outlicensed animal health franchise

Risk mitigation:

- Include carefully crafted term and termination scenarios that address concerns before value is lost
- Include mechanism for reporting requirements and transition of product in the event of certain metrics not being met
- Monitor, monitor, monitor
  - For indications of patent erosion
  - For product development status
  - For important corporate changes

Example – Term Tied to Company Health

- Term. The Agreement shall have an initial term of five (5) years, renewable automatically thereafter in twenty-four (24) month increments, provided, that at the end of the initial 5-year term and each renewal term thereafter, the Agreement shall not renew with respect to one or more specified Products (each, a “Terminated Product”)(but shall renew with respect to all other Products) if either

Example – Term Tied to Company Health (cont.)

(A) the Distributor gives twelve (12) months advance notice of nonrenewal for such Terminated Product(s) or

(B) both (i) Company gives twelve (12) months advance notice of nonrenewal for such Terminated Product and (ii) the Distributor's average annual sales for the entire suite of Products then subject to this Agreement was less than $XX,000,000 per annum on average in the two (2) Contract Years immediately prior to expiration of the then-current term of this Agreement ($XX,000,000 per annum on average after the 10th anniversary of the Effective Date, increasing annually thereafter by the PPI Adjustment).

Questions?

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